REMARKS

Applicant respectfully requests that the Examiner enter and consider the amendments and remarks filed on June 24, 2003 in addition to the amendments and remarks in this supplemental amendment.

Rejections regarding deposit

In the Advisory Action, the Examiner states that Applicant is required to provide evidence of deposit either under the Budapest Treaty and/or to satisfy criteria set forth in 37 C.F.R. §§ 1.801-1.809.

In response, Applicant submits a copy of hybridoma cell line deposit certificates (attached as Exhibit A) for the hybridoma cell lines CCTCC-C200305, CCTCC-C200306, CCTCC-C200307, and the certificates state that these hybridoma cell lines were deposited at China Center for Type Culture Collection at Wuhan University, Wuhan 430072, P.R. China on June 10, 2003. These deposits were made under Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and the strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive. Also submitted with this supplemental amendment is a declaration pursuant to 37 C.F.R. § 1.809(b)(1) stating that the biological materials assigned CCTCC-C200305, CCTCC-C200306, CCTCC-C200307 are biological materials specifically identified in the present application and that the hybridoma cell lines will be irrevocably and without restriction or conditions released to the public upon issuance of a patent.

Therefore, the deposit of these three hybridoma cell lines that produce the antibodies in the claims satisfy the requirement under 37 C.F.R. §§ 1.801-1.809. Applicant respectfully requests that the rejection be withdrawn.

Rejections under 35 U.S.C. § 112

Written description

Claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-143 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserted that:

- the disclosure of an antibody to a protein of 55 kDa on the surface of one type of hepatocellular carcinoma cell line is insufficient to describe the genus as broadly claimed;
- as is the disclosure of four bridge molecules that is are all bispecific antibodies;
- as is the lack of disclosure of one or more primary or costimulatory T cell activation molecules on the surface of T cells of said patient mammal as a component of the claimed composition.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, applicant has amended the independent claim 103 to recite "said gp55 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200305, said gp95 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200306, and said gp210 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200307, respectively." It is respectfully submitted that the written description rejection based on the alleged insufficient description of gp55 antigen is rendered moot by the above amendment (*See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2D (BNA) 1609 (Fed. Cir. 2002) holding that in light of the history of biological deposits for patent purposes, the goals of

the patent law, and the practical difficulties of describing unique biological materials in a written description, reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1). The other two grounds for the written description rejection are also rendered moot by the amendments of claim 103.

Enablement

Claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-143 are rejected under 35 U .S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, the Examiner asserted that the specification does not disclose how to make and/or use the instant invention on three grounds:

(1) making and using antibodies to any 55 kDa glycoprotein, i.e., "gp55", on the surface of any isolated autologous target autologous target carcinoma or lymphoma cells;

(2) making and using a composition comprising a bridge molecule that is not a bispecific antibody; and

(3) making and using a composition further comprising one or more primary or costimulatory T cell activation molecules on the surface of T cells in said patient mammal.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, applicant has amended the independent claim 103 to recite "said gp55 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200305, said gp95

antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200306, and said gp210 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200307, respectively." It is respectfully submitted that the enablement rejection based on the alleged insufficient teaching of gp55 binding antibody is rendered moot by the above amendment. The other two grounds for the non-enablement rejection are also rendered moot by the amendments of claim 103.

Indefiniteness

Claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-143 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner made the following specific rejections:

a. Claims 107, 114, 121-124, 126, 128 and 114 recite the limitation "said one or more hepatocellular carcinoma, lymphoma or colorectal carcinoma cells". There is insufficient antecedent basis for this limitation in the claim.

b. Claims 110-114 recite the limitation "said one or more CD28 or 4-1BB molecules". There is insufficient antecedent basis for this limitation in the claims.

c. Claims 112 and 113 recite the limitation "said one or more hepatocellular carcinoma, or colorectal carcinoma cells". There is insufficient antecedent basis for this limitation in the claim.

d. Claims 118, 128 and 131 recite the limitation "said one or more target hepatocellular carcinoma, lymphoma or colorectal carcinoma cells". There is insufficient antecedent basis for this limitation in the claim.

e. Claims 110-114, 130 and 132 recite the limitation "said one or more CD28 or 4-1BB molecules". There is insufficient antecedent basis for this limitation in the claim.

f. Claim 143 is indefinite in the recitation of "bridge molecule further comprises bispecific monoclonal antibody" because it is not clear what is meant, i.e., is the bridge molecule a bispecific monoclonal antibody? In addition, the article "a" appears to, be missing after "comprises".

g. Claims 129, 131 and 141 are indefinite in the recitation of antibodies which comprise "two or more" or "one or more" "antigen binding sites for one or more gp55 antigens on the surface of said one or more target hepatocellular carcinoma, lymphoma or colorectal carcinoma cells" or "one or more binding sties for antigen gp55" because the characteristics of the said gp55 antigens and hence, that of the said antibodies, are not known. The use of "gp55" as the sole means of identifying the protein to which the claimed antibody is specific renders the claim indefinite because "gp55" is merely a laboratory designation which does not clearly define the claimed product, since the said designation is merely a characterization of a protein by size and may refer to many different proteins.

It is respectfully submitted that these rejections are rendered moot by the amendments of claims 103, 107, 110-114, 118, 119, 121-124, 126, 128-133, 135, 136, 140 and 141.

It is respectfully submitted that the rejection of claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-143 under 35 U.S.C. § 112 is overcome by the above remarks and/or amendments and must be withdrawn.

CONCLUSION

Applicant submits that the rejections of claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-143 under 35 U.S.C. § 112 have been overcome by the above remarks and/or amendments. Early allowance of the pending claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-145 are earnestly requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **532732000200**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: Nov. 24, 2003

Respectfully submitted,

By: _____

Peng Chen
Registration No. 43,543

Morrison & Foerster LLP
3811 Valley Centre Drive
Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-5117
Facsimile: (858) 720-5125